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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 70**

**Food and Drug Administration**

**21 CFR Part 1240**

**[Docket No. 00N-1317]**

**Control of Communicable Diseases; Apprehension and Detention of Persons With Specific Diseases; Transfer of Regulations**

**AGENCIES:** Food and Drug Administration and Centers for Disease Control and Prevention, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Secretary of Health and Human Service (the Secretary) is transferring a portion of the Food and Drug Administration (FDA) "Control of Communicable Diseases" regulations to the Centers for Disease Control and Prevention (CDC). In general, these regulations provide the Secretary with the authority to apprehend, detain, or conditionally release individuals to prevent the spread of specified communicable diseases. The regulations implement the provisions of the Public Health Service Act (PHS Act) to prevent the introduction, transmission, or spread of communicable diseases from one State or possession into any other State or possession. CDC will have authority for interstate quarantine over persons, while FDA will retain regulatory authority over animals and other products that may transmit or spread communicable diseases. The Secretary is taking this action to consolidate regulations designed to control the spread of communicable diseases, thereby increasing the agencies' efficiency and effectiveness.

**DATES:** This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for CDC.

**FOR FURTHER INFORMATION CONTACT:**

James E. Barrow, National Center for Infectious Diseases (E-03), Centers for Disease Control and Prevention, 1600 Clifton Rd. NE., Atlanta, GA 30333, 404-639-8107; or

Captain Lawrence C. Edwards, Retail Food and Interstate Travel Team (HFS-627), Food and Drug Administration, 200 "C" St. SW., Washington DC 20204, 202-205-8280.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Under sections 361 and 369 of the PHS Act, as amended, the Secretary issues and enforces regulations necessary to prevent the introduction, transmission, or spread of communicable diseases in the United States. FDA and CDC have been delegated regulatory responsibility under these provisions. The regulations contained in part 1240 (21 CFR part 1240), pertain to interstate control of communicable diseases and are currently administered by FDA. Regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States are currently administered by CDC in 42 CFR part 71. The Secretary is taking this action to consolidate regulations designed to control the spread of communicable diseases, thereby increasing the agencies' efficiency and effectiveness.

The Secretary is transferring regulatory authority contained in the following sections of 21 CFR part 1240 to CDC: Section 1240.3 introductory text and paragraphs (b), (c), (e), (g), (h), (l), (n), and (p); § 1240.30; and Subpart C—Restrictions on Travel of Persons (consisting of §§ 1240.40, 1240.45, 1240.50, 1240.54, 1240.55, and 1240.57). The transferred regulations will be sequentially renumbered in 42 CFR part 70. In addition, "Director of the Centers for Disease Control and Prevention" has been inserted in new 42 CFR 70.2 in place of "Commissioner of Food and Drugs," currently in 21 CFR 1240.30.

Although regulatory authority with respect to interstate quarantine over persons in §§ 1240.3, 1240.30, and 1240.45 is being transferred to CDC, FDA is retaining its regulatory authority in §§ 1240.3, 1240.30, and 1240.45 with respect to animals and other products that may transmit or spread communicable diseases, to ensure that FDA's Center for Food Safety and Applied Nutrition has the necessary authorities to prevent the spread of disease from any conveyance engaged in interstate travel or in the event of inadequate local control. Current § 1240.45 is also being moved to 21 CFR part 1240, subpart B (Administrative Procedures), and subpart C is being removed and reserved. The Secretary is issuing this rule without publishing a general notice of proposed rulemaking because such a notice is not required for this rule of agency organization, procedure, or practice under 5 U.S.C. 553(b)(A).

Table 1 reflects the actions the Secretary is taking:

TABLE 1

Current 21 CFR Sections (FDA)	New 42 CFR Sections (CDC)
1240.3 introductory text, and paragraphs (b), (c), (e), (g), (h), (l), (n), and (p) transferring and retaining.	70.1
1240.30 transferring and retaining .....	70.2
1240.40 transferred to .....	70.3
1240.45 transferring and retaining .....	70.4
1240.50 transferred to .....	70.5
1240.54 transferred to .....	70.6
1240.55 transferred to .....	70.7
1240.57 transferred to .....	70.8

This transfer of authority does not affect other authority exercised by FDA under sections 361 and 369, or any other sections, of the PHS Act.

## II. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. In the absence of an applicable categorical exclusion, CDC conducted an environmental assessment of this transfer of authority in accordance with the Department of Health and Human Services administrative guidance and determined that the transfer presented no significant impact on the human environment.

### **III. Federalism**

Executive Order 13132 applies when agencies formulate or implement policies or regulations that preempt State law or that have federalism implications. Executive Order 13132 provides that agencies are to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and assess carefully the need for such actions. FDA and CDC have examined this rule and have determined that it does not preempt State law and it does not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Rather, the Secretary is taking this action to consolidate regulations to control the spread of communicable diseases, thereby increasing the agencies' efficiency and effectiveness. Therefore, no further action is required by Executive Order 13132.

### **IV. Analysis of Impacts**

FDA and CDC have examined the impacts of this rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or more, or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agencies find that this final rule, which transfers existing regulatory authority from one agency to the other, is not a significant rule as defined by Executive Order 12866. No analysis is required under the Regulatory Flexibility Act (5 U.S.C. 601–612) because the Secretary is issuing it without publishing a general notice of proposed rulemaking, as explained previously in this document.

## **V. Paperwork Reduction Act of 1995**

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In the **Federal Register** of April 12, 2000 (65 FR 19772), CDC published a document entitled “Proposed Data Collections Submitted for Public Comment and Recommendations” to collect information under those regulations, and sought public comment for 60 days. The comment period closed on June 12, 2000. CDC will now prepare an information collection request for submission to OMB, and will publish another document in the **Federal Register** announcing submission of the request to OMB and soliciting that comments be submitted to OMB. CDC will publish an additional document in the **Federal Register** announcing OMB’s decision to approve, modify, or disapprove the information collection provisions of this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

### **List of Subjects**

#### *21 CFR Part 1240*

Communicable diseases, Public health, Travel restrictions, Water supply.

## 42 CFR Part 70

Communicable diseases, Public health, Quarantine, Reporting and recordkeeping requirements, Travel restrictions.

Therefore, under the Public Health Service Act, 21 CFR Chapter I and 42 CFR Chapter I are amended as follows:

## 21 CFR Chapter I

### PART 1240—CONTROL OF COMMUNICABLE DISEASES

1. The authority citation for 21 CFR part 1240 continues to read as follows:

**Authority:** 42 U.S.C. 216, 243, 264, 271.

#### § 1240.45 [Transferred from Subpart C to Subpart B]

2. Section 1240.45 *Report of disease* is transferred from subpart C to subpart B.

#### Subpart C [Removed and Reserved]

3. Subpart C is removed and reserved.

## 42 CFR Chapter I

4. Part 70 is added to subchapter F of Chapter I to read as follows:

### PART 70—INTERSTATE QUARANTINE

Secs.

- 70.1 General definitions.
- 70.2 Measures in the event of inadequate local control.
- 70.3 All communicable diseases.
- 70.4 Report of disease.
- 70.5 Certain communicable diseases; special requirements.
- 70.6 Apprehension and detention of persons with specific diseases.

70.7 Responsibility with respect to minors, wards, and patients.

70.8 Members of military and naval forces.

**Authority:** 42 U.S.C. 216, 243, 264, 271.

## **§ 70.1 General definitions.**

As used in this part, terms shall have the following meaning:

(a) *Communicable diseases* means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(b) *Communicable period* means the period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(c) *Conveyance* means any land or air carrier, or any vessel as defined in paragraph (h) of this section.

(d) *Incubation period* means the period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestation of the disease.

(e) *Interstate traffic* means:

(1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(i) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(ii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(f) *Possession* means any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(g) *State* means any State, the District of Columbia, Puerto Rico, and the Virgin Islands.

(h) *Vessel* means any passenger-carrying, cargo, or towing vessel exclusive of:

- (1) Fishing boats including those used for shell-fishing;
- (2) Tugs which operate only locally in specific harbors and adjacent waters;
- (3) Barges without means of self-propulsion;
- (4) Construction-equipment boats and dredges; and
- (5) Sand and gravel dredging and handling boats.

#### **§ 70.2 Measures in the event of inadequate local control.**

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

#### **§ 70.3 All communicable diseases.**

A person who has a communicable disease in the communicable period shall not travel from one State or possession to another without a permit from the health officer of the State, possession,



or locality of destination, if such permit is required under the law applicable to the place of destination. Stop-overs other than those necessary for transportation connections shall be considered as places of destination.

#### **§ 70.4 Report of disease.**

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

#### **§ 70.5 Certain communicable diseases; special requirements.**

The following provisions are applicable with respect to any person who is in the communicable period of cholera, plague, smallpox, typhus or yellow fever, or who, having been exposed to any such disease, is in the incubation period thereof:

(a) *Requirements relating to travelers.* (1) No such person shall travel from one State or possession to another, or on a conveyance engaged in interstate traffic, without a written permit of the Surgeon General or his/her authorized representative.

(2) Application for a permit may be made directly to the Surgeon General or to his/her representative authorized to issue permits.

(3) Upon receipt of an application, the Surgeon General or his/her authorized representative shall, taking into consideration the risk of introduction, transmission, or spread of the disease from one State or possession to another, reject it, or issue a permit that may be conditioned upon compliance with such precautionary measures as he/she shall prescribe.

(4) A person to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances as required by its terms.

(b) *Requirements relating to operation of conveyances.* (1) The operator of any conveyance engaged in interstate traffic shall not knowingly:

(i) Accept for transportation any person who fails to present a permit as required by paragraph (a) of this section; or

(ii) Transport any person in violation of conditions prescribed in his/her permit.

(2) Whenever a person subject to the provisions of this section is transported on a conveyance engaged in interstate traffic, the operator thereof shall take such measures to prevent the spread of the disease, including submission of the conveyance to inspection, disinfection and the like, as an officer of the Public Health Service designated by the Surgeon General for such purposes deems reasonably necessary and directs.

#### **§ 70.6     Apprehension and detention of persons with specific diseases.**

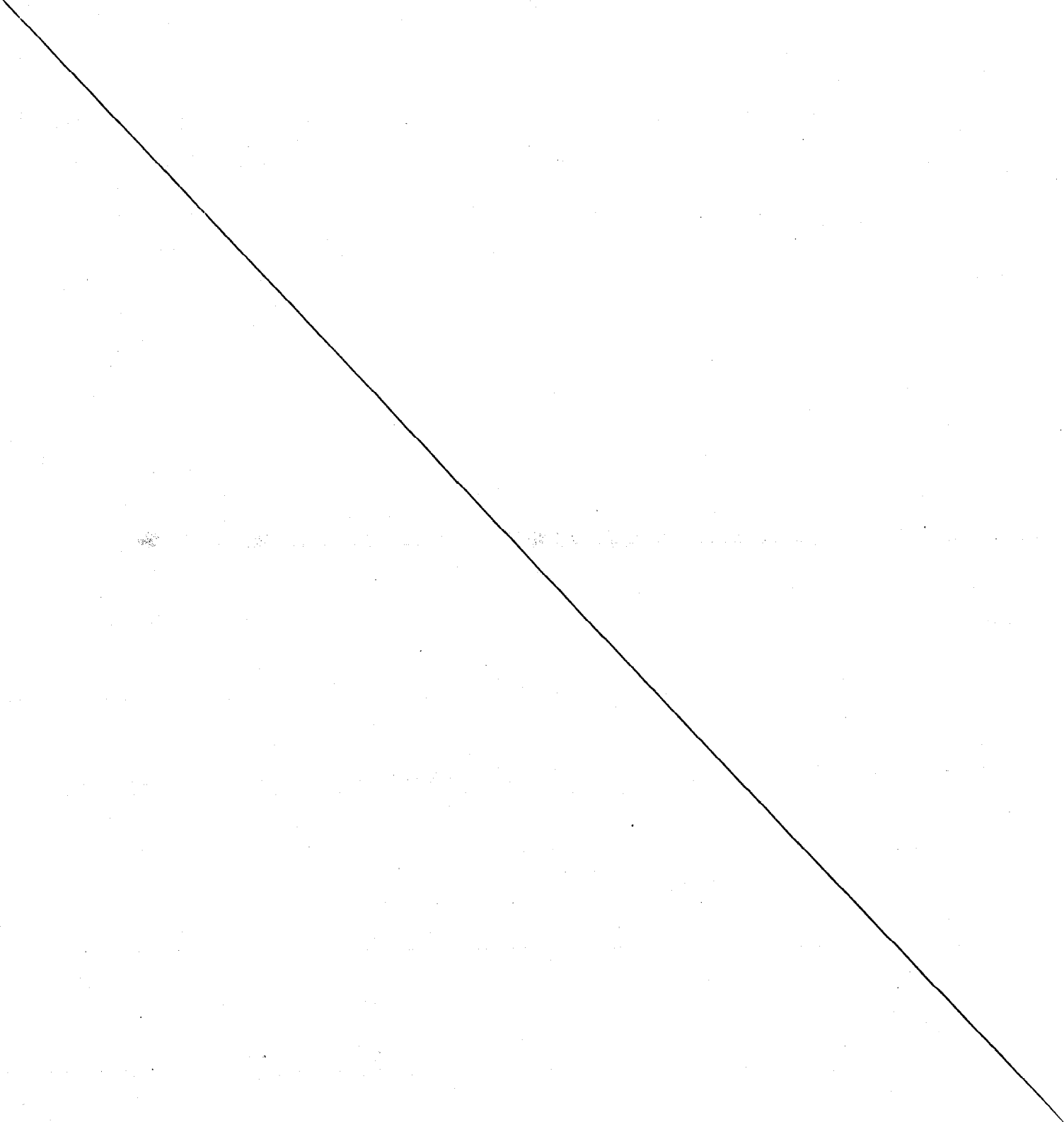
Regulations prescribed in this part are not applicable to the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of the following diseases: Anthrax, chancroid, cholera, dengue, diphtheria, granuloma inguinale, infectious encephalitis, favus, gonorrhea, leprosy, lymphogranuloma venereum, meningococcus meningitis, plague, poliomyelitis, psittacosis, relapsing fever, ringworm of the scalp, scarlet fever, streptococcic sore throat, smallpox, syphilis, trachoma, tuberculosis, typhoid fever, typhus, and yellow fever.

#### **§ 70.7     Responsibility with respect to minors, wards, and patients.**

A parent, guardian, physician, nurse, or other such person shall not transport, or procure or furnish transportation for any minor child or ward, patient or other such person who is in the communicable period of a communicable disease, except in accordance with provisions of this part.

**§ 70.8 Members of military and naval forces.**

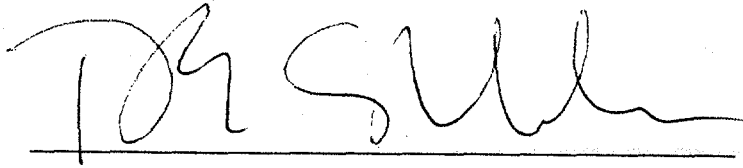
The provisions of §§ 70.3, 70.4, 70.5, 70.7, and this section shall not apply to members of the military or naval forces, and medical care or hospital beneficiaries of the Army, Navy, Veterans' Administration, or Public Health Service, when traveling under competent orders: *Provided, That*



in the case of persons otherwise subject to the provisions of § 70.5 the authority authorizing the travel requires precautions to prevent the possible transmission of infection to others during the travel period.

AUG - 8 2000

Dated: \_\_\_\_\_  
August 8, 2000



**Donna E. Shalala,**

*Secretary of Health and Human Services.*

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